DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 February 2009 has been entered.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 07 April 2003. It is noted, however, that IB has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

Claim Status

Claims 1, 3-13 are active in the case. Claim 2 has been cancelled. Claims 1, 3-5 and 11-13 are under examination; claims 6-10 are withdrawn at this time as drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The amendment to the independent claim recites that the second container "defines" a first volume of air between the second opening of the transfer means and the at least one system for detecting said bacteria, however, the original claim language, the amendment is based on cancelled claim 2 and deleted language from claim 3, and the specification language recite that "[]preferably, the second container delimits a first volume of air between the second opening and the detection system and/or the transfer means delimits a second volume of air between the first opening and the second opening. If the second container also comprises, between the second opening of the transfer means and the detection system, a selective medium, the volume of air is preferably delimited between the second opening of the transfer means and the selective medium" [0027]. There is no description in the original specification or claims of the word "defines", the original disclosure uses the word "delimits" and there is no disclosure of any relationship or equivalence between the two words. Removal of the new matter is required.

Claims 1, 3-5, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. This is a new matter rejection. The amendment to the independent claim recites that a first volume of air is "defined" between the second opening of the transfer means and the at least one system for detecting said bacteria, however the prior claim language, from which the amended language is taken, recites that the second container delimits a first volume of air between the second opening and the detection system and/or the transfer means delimits a second volume of air between the first opening and the second opening. In the specification there is no support for language other than the alternative "and/or". There is no support for choosing either of the alternatives alone or support for why one alternative would be chosen over the other. Removal of the new matter is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holbrook (EP 0 295 116), Taylor et al. (WO 2000/63668 and 6,605,475) and Grant et al. (US 5624815). Holbrook teaches apparatus and methods for microorganism culture and testing comprising liquid medium in a Stomacher device (page 9 line 11), with one or more tube carriers dipping into the liquid media, but projecting above the liquid media surface (claim 1), where the carrier tubes are loaded with appropriate media and in contact with the medium in the culture vessel (page 9 lines19-22), at a temperature of 37 °C to 41.5 °C (page 9, line 23). Holbrook allows the bacteria to move from the liquid media being tested into the supported media during the testing period (claim 1). Holbrook also contemplates at least two supported media in series (claim 3).

Taylor et al. (WO) disclose apparatus and methods developed to automatically deliver samples to reaction vessels, analytical devices or any location where sample introduction is desired (page 2, lines 8-12). They use channels, e.g., capillaries, with temperature control devices in communication with the channels allowing the heating/cooling of the capillaries to control the movement of the reagents via pressure changes (page 2). As well, they contemplate

the use of one or more temperature control devices to heat and/or cool the entire capillary or discrete locations (page 3, lines 8-12). In paragraph three on pages three, Taylor et al. disclose the theory behind the use of temperature controls and temperature changes. They reveal that "an aliquot of sample is drawn into the capillary to fill the volumetric void left by the contracting gas when the system is cooled" (page 3, line 22). They particularly disclose a preferred embodiment wherein a sample delivery system is used to introduce a sample into a sample analysis apparatus (page 3. lines 29-31).

Taylor et al. (US) disclose "[a]pparatus and methods now have been developed to deliver automatically a sample to a reaction vessel, an analytical device or any location where sample introduction or deposition is desired. Broadly, the invention relates to a thermally-controlled microscale sample delivery system and methods of its use. An embodiment of the invention includes apparatus and methods for delivery of a sample to a channel wherein chemical reactions occur. A sample delivery system of the invention generally comprises a housing defining a channel, e.g., a capillary, and a temperature control device in thermal communication with the channel. The channel preferably is closed at one end, and contains an opening for introduction of a sample. The closed end typically is associated with the temperature-control device. The temperature control device may be a thermoelectric heater, such as a Peltier element, for heating and cooling a thermally expandable fluid in the channel. The temperature control device also may include a temperature controlled fluid which is in thermal communication the channel" (col. 1-2, bridging paragraph). They teach that the sample delivery system may be "used in applications to detect toxins (e.g., bacteria, alcohol, drugs, viruses, organisms, metals, abnormal levels of physiological chemicals, and the like), or other components in a sample (e.g., a

biological or environmental sample)" (col. 4, lines 60-65). Also, they teach "the volume of sample charged into the capillary is a preselected or metered aliquot which typically is determined by the amount of time the capillary … is immersed in the sample … and the pressure differentials acting on the sample. Subsequently, the aliquot of sample … which is drawn into the capillary may be deposited elsewhere for further reaction and/or analysis" (col. 12, lines 15-21).

Grant et al. teach a "method for analyzing solid material in a liquid sample, which comprises the steps of: substantially uniformly distributing the sample by passage through a plurality of discrete wells provided in an integral member and whose bases are defined by filter material that retains the solid material and allows the passage of liquid, the concentration of solid material being such that it is absent in at least one well; and analyzing the wells for the presence of retained solid material" (claim 1). As well as a "device adapted for use in a method for analyzing solid material in a liquid sample comprises the combination of: a container for the sample; a unit comprising a number of discrete wells adapted to retain the solid material and allow the passage of liquid under the application of reduced pressure; structure for drawing liquid from the container and through the wells under reduced pressure; and a manifold or other element that provides uniform distribution of the sample passing from the container into the wells" (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Holbrook, Taylor et al. (WO and US) and Grant et al. to achieve the invention as described. Separation of a sample for the purposes of analyzing a suspected microbacterial component is described by Holbrook, Taylor et al. (WO and US) and

Grant et al. While Holbrook teaches allowing the bacteria to move into the test system under their own motile power, Grant et al. teach using reduced pressure created by suction and Taylor et al. teach using temperature, heating and cooling, to create the pressure gradients necessary to move liquid samples among test containers. Each of these references teaches that the sample containers must be open to each other, to allow movement of the samples to be tested, and each teaches a variety of temperatures for the assays, as well as Taylor et al. teaching the use of heating and cooling temperatures to control the pressure of the containers and the movement of the sample fluids. Taylor et al. teach that defined volumes of liquid may be moved by controlling the size of the capillary tube. One would be motivated to do sample testing assays and have a reasonable expectation of success because of the importance to the health care community and pharmaceutical industry of selective testing for bacteria and the specificity of the teachings of the cited references, among many others, disclosing the mechanics of selective bacterial assays.

Art of Record

The examiner notes the following prior art not relied upon in a rejection: N. Pautz DE 19605753, 04 September 1997. According to the abstract provided, Pautz teaches a method for detecting bacteria in a sample wherein a reaction vessel comprises a growth culture of a microorganism. Subsequently, metabolic products from the culture are collected separately from the bacteria and nutrient broth and analyzed to determine the presence or absence of bacteria. He apparently does not teach the movement of bacteria between reaction chambers.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

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